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EXAMINER	
PAULS, JOHN A	

ART UNIT	PAPER NUMBER
3686	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,553	SHAH, RAJESH NAVANITAL	
	Examiner	Art Unit	
	JOHN A. PAULS	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *18 January, 2005 and 25 July, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 23 October, 2003.

2. Claims 1 - 47 are currently pending and have been examined.

Information Disclosure Statement

3. The Information Disclosure Statements filed on 18 January, 2005 and 25 July, 2006 have been considered. Initialed copies of the Form 1449 are enclosed herewith.

Claim Objections

4. Claims 9 and 10 are objected to because of the following informalities: Claims 9 and 10 recite a dependence to claim 8 when they should properly recite a dependence to claim 8.

5. Claims 14 and 15 are objected to because of the following informalities: Claims 14 and 15 recite a dependence to claim 12 when they should properly recite a dependence to claim 13.

6. Claim 17 is objected to because of the following informalities: Claim 17 recites a dependence to claim 15 when it should properly recite a dependence to claim 16.

7. Claim 31 is objected to because of the following informalities: Claim 31 recites a dependence to claim 29 when it should properly recite a dependence to claim 30.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "*helps*" in claim 9 is a relative term which renders the claim indefinite. The term "*helps*" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

10. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "*tight*" in claim 10 is a relative term which renders the claim indefinite. The term "*tight*" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 21 – 47 are rejected under 35 U.S.C. 101 because the steps recited do not qualify as a statutory process. In order for a method to be considered a "process" under §101, a claimed process must either: (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials). Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972). If neither of these requirements is met by the claim, the method is not a patent eligible process under §101 and is non-statutory subject matter. Although the steps are performed using a computer, the computer is a field of use limitation because the steps are human actions that do not require (i.e. are not tied to) the computer.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1 – 11, 13 – 20, 21, 22 and 32 - 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Thangaraj et al. (WO 01/093160 A1).

CLAIM 1

Thangaraj as shown discloses a clinical trial management system with the following limitations:

- *a Web client, wherein the Web client can access the Web via a Web browser;* (see at least Thangaraj page 4 line 13 – 19 and page 10 line 24 – 28);
- *a client;* (see at least Thangaraj page 4 line 13 – 19 and page 10 line 24 – 28);
- *a server, wherein the Web client can access the server via a Web connection and the client can access the server via a connection other than the Web connection;* (see at least Thangaraj page 3 line 10 – 17 and page 4 line 9 – 10);
- *a patient records database, wherein the patient records database can be accessed by the server and the patient records database is logically partitioned and distributed based on a role in the clinical trials process of a user accessing the information;* (see at least Thangaraj page 3 line 24 – 30; page 3 line 35 to page 4 line 2 and page 4 line 13 – 19).

CLAIMS 2 - 11

Thangaraj as shown discloses the limitations shown above relative to Claim 1. Thangaraj also discloses the following limitations:

- *a computer, a cellular telephone, and a personal data assistant;* (see at least Thangaraj page 4 line 13 – 19 and page 15 line 30 to page 16 line 16);
- *the user comprises one or more of sponsor, regulator, investigator, site, patient, and monitor;* (see at least Thangaraj page 3 line 10 – 17 and page 9 line 32 to page 10 line 7);
- *a trial design application, wherein the trial design application allows a clinical trial to be designed, developed, and customized;* (see at least Thangaraj page 12 line 24 – 34);

- *a trial conduct application, wherein the trial conduct application manages ongoing operations of the clinical trial;* (see at least Thangaraj page 10 line 8 – 14 and page 12 line 24 – 34);
- *a trial monitoring application, wherein the trial monitoring application provides information about the ongoing operations of the clinical trial at a moment in time during the clinical trial;* (see at least Thangaraj page 12 line 24 – 34);
- *a trial analysis application, wherein the trial analysis application provides information about the results of the clinical trial up to the time the trial analysis application is accessed;* (see at least Thangaraj page 10 line 8 – 14 and page 12 line 24 – 34);
- *a trial closure application, wherein the trial closure application performs a function to close-out the clinical trial;* (see at least Thangaraj page 12 line 24 – 34);
- *a portal application, wherein the portal application provides a user interface accessible through the Web connection;* (see at least Thangaraj page 10 line 8 – 14 and page 12 line 24 – 34);
- *a commercial off-the-shelf software application, wherein the commercial off-the-shelf software application integrates external software used by the system;* (see at least Thangaraj page 11 line 5);
- *a good clinical information application, wherein the good clinical information application assures that collected data is compliant with industry regulations and standards, is in accordance with an organizational workflow and the clinical trial critical path, adheres to data integrity standards, and is maintained in accordance with security*

and privacy standards; (see at least Thangaraj page 2 line 31 – 32; page 3 line 5 – 8 and line 24 – 30; page 5 line 13 - 19 and page 12 line 24 – 34);

- *an applications interface application, wherein the applications interface application allows the client to access the system;* (see at least Thangaraj page 10 line 35 to page 11 line 5);
- *a security application, wherein the security application allows user-defined password-protected access to the data and assures the security and integrity of the data while maintaining the compatibility with industry standards and regulations;* (see at least Thangaraj page 3 line 5 – 8);
- *the trial submission application assembles information required for regulatory submissions and generates reports for regulatory reporting;* (see at least Thangaraj page 11 line 15 – 19; page 5 line 13 - 19 and page 12 line 24 – 34);
- *industry standards and regulations comprise one or more of the Health Level 7, 21 CFR Part 11, Health Insurance Portability and Accountability Act (1996), and American Society for Testing and Materials requirements;* (see at least Thangaraj page 9 line 25 – 30);
- *a dictionary and standards component, wherein the dictionary and standards component enables interfaces between the system and relevant dictionaries and standards comprising one or more of common data elements, common toxicity criteria, MedDRA codes, ICD9/10 codes, IMT codes, and Common Data Interchange Standards Consortium;* (see at least Thangaraj page 24 line 5 – 14);

- *a clinical development planner component, wherein the clinical development planner component assists in identification of clinical trial candidates for development and helps in creating target product profiles;* (see at least Thangaraj page 20 line 10 – 15);
- *a protocol manager component, wherein the protocol manager component allows the definition of all elements of the clinical trial in a collaborative manner with tight document control;* (see at least Thangaraj page 3 line 10 – 17 and page 4 line 9 – 10);
- *a change management system component, wherein the change management system component allows for the implementation of clinical quality assurance and control through the ability to revise, version, and track modifications and approvals on controlled documents comprising one or more of protocols, informed consents, ease reports forms, investigative brochures, patient materials, and advertising and marketing materials;* (see at least Thangaraj page 19 line 27 – 32);
- *a subject registration manager component, wherein the subject registration manager component registers patients and profiles them against clinical trial inclusion and exclusion criteria for appropriate patient recruitment, allows for the collection of demographic, payer, referring physician, and emergency information as one portion of the complete clinical trial-related electronic medical record, and captures information about the referring physician for the purposes of evaluating investigative site performance, gathering patient population characteristics, and maintaining a two-way flow of information pertaining to the patients medical condition and progress through the trial;* (see at least Thangaraj page 20 line 10 – 15);

- *a financial account manager component, wherein the financial account manager component enables gate-keeping of medical billing to assure appropriate billing practices in the context of clinical research;* (see at least Thangaraj page 19 line 13 – 26);
- *an investigation agent manager component, wherein the investigational agent manager component allows the capture of all drug distribution, tracking, disposition, accountability, transfer, and return in accordance with regulations and a clinical trial protocol; a patient evaluation manager component, wherein the patient evaluation manager component facilitates interpretive summaries, diagnosis code assignment, and treatment code assignment to allow for assurance of compliance with the clinical trial protocol, proper study visit documentation, streamlined serious adverse event reporting, and clinical outcome evaluation; a treatment regimen manager component, wherein the treatment regimen manager component allows for a standardized mechanism for treatment courses and dose escalations in accordance with algorithms that are configured in accordance with the clinical trial protocol; a clinical data import manager component, wherein the clinical data import manager component allows interface with radiology imaging systems for import of radiographic data and diagnostic interpretations, medical information systems for import of medical data, and medical information systems for import of laboratory data for the clinical trial;* (see at least Thangaraj page 11 line 26 – 33);
- *an auto encoding component, wherein the auto encoding component codes disease categories and toxicity data through access to current global libraries and coding*

algorithms; an adverse event manager component, wherein the adverse event manager component collects and tracks all adverse events in the clinical trial process; (see at least Thangaraj page 20 line 16 – 20 and page 22 line 5 – 8).

CLAIMS 13 - 20

Thangaraj as shown discloses the limitations shown above relative to Claim 1. Thangaraj also discloses the following limitations:

- *a trial monitoring application comprising one or more of a database snapshot generator component, wherein the database snapshot generator component enables access to data for real-time clinical trial status monitoring at definable intervals for resource allocation, trend analysis, decision support, and interim analysis; and a subject status manager component, wherein the subject status manager component ascertains the status of all subjects in the clinical trial and captures reasons subjects leave the clinical trial;* (see at least Thangaraj page 20 line 21 – 24);
- *the trial monitoring application further comprises a monitor and auditor manager component, wherein the monitor and auditor manager component assures compliance with regulations requiring specific monitoring and auditing of the clinical trial process;* (see at least Thangaraj page 20 line 25 – 31);
- *the trial monitoring application further comprises a case report form manager component, wherein the case report form manager component allows the design and tracking of paper and electronic case report forms;* (see at least Thangaraj page 20 line 21 – 31);

- *the trial analysis application comprises a clinical outcome manager component, wherein the clinical outcome manager component generates interim and final clinical trial status reports;* (see at least Thangaraj page 20 line 21 – 24);
- *the trial analysis application further comprises an executive information manager component, wherein the executive information manager component allows for the monitoring of key executive vital signs, data analysis, and business intelligence;* (see at least Thangaraj page 19 line 13 – 26);
- *the applications interface application comprises: an application programming interface component, wherein the application programming interface component enables external applications to communicate with the system; and an XML Data Pump component, wherein the XML Data Pump component allows import and export of data in XML format to and from the patient records database;* (see at least Thangaraj page 17 line 33 to page 18 line 2 and page 22 line 18 – 32);
- *the applications interface application further comprises a mobile connectivity component, wherein the mobile connectivity component allows mobile devices to enter and retrieve data as the client;* (see at least Thangaraj page 15 line 30 to page 16 line 16 and page 17 line 20 – 32);
- *the applications interface application further comprises a patient records manager component, wherein the patient records manager component allows external electronic medical records to be added to the clinical trials process, which provides the system with*

demographic information; (see at least Thangaraj page 14 line 33 to page 15 line 18 and page 18 line 18 – 25).

CLAIM 21

Thangaraj as shown discloses a clinical trial management system with the following limitations:

- *creating reporting requirements for a stakeholder;* (see at least Thangaraj page 20 line 21 - 24);
- *extracting data from the system based on the reporting requirements;* (see at least Thangaraj page 10 line 8 - 14);
- *validating the data against regulations and standards;* (see at least Thangaraj page 11 line 15 - 19);
- *creating information from the data based on what is known about the stakeholder;* (see at least Thangaraj page 13 line 14 - 33);
- *displaying the information to the stakeholder;* (see at least Thangaraj page 13 line 14 - 33).

CLAIM 22

Thangaraj as shown discloses the limitations shown above relative to Claim 21. Thangaraj also discloses the following limitations:

- *the stakeholder comprises on of sponsor, regulator, investigator, site, patient, and monitor;* (see at least Thangaraj page 3 line 10 – 17 and page 9 line 32 to page 10 line 7).

CLAIM 23

Thangaraj as shown discloses a clinical trial management system with the following limitations:

23. A method for monitoring events within a system for managing clinical trials, the method comprising:

- *performing an event in a clinical trials protocol;* (see at least Thangaraj page 5 line 13 - 19);
- *checking the event against business logic rules, industry regulations, and industry standards;* (see at least Thangaraj page 9 line 25 – 30; page 11 line 15 – 19 and page 19 line 27 - 32);
- *alerting at least one stakeholder of the event;* (see at least Thangaraj page 23 line 28 - 34).

CLAIM 32

Thangaraj as shown discloses a clinical trial management system with the following limitations:

- *assuring that clinical information is collected in compliance with regulatory requirements;* (see at least Thangaraj page 25 line 5 - 15);

- *assuring that the clinical information is collected in accordance with a proper organization workflow;* (see at least Thangaraj page 15 line 12 – 18 and page 19 line 27 - 32);
- *assuring that the clinical information is collected according to a clinical trial critical path;* (see at least Thangaraj page 15 line 12 - 18);
- *assuring data integrity of the clinical information; assuring the security of the clinical information; and assuring the privacy of the clinical information;* (see at least Thangaraj page 3 line 5 - 8).

CLAIMS 33 - 37

Thangaraj as shown discloses the limitations shown above relative to Claim 32. Thangaraj also discloses the following limitations:

- *assuring consistency with regulations from one or more of the International Conference on Harmonization Good Clinical Practice, the Code of Federal Regulations, the Office of Human Research Protections, and the National Institutes of Health;* (see at least Thangaraj page 25 line 5 - 15);
- *assuring that the clinical information in accordance with a proper organization workflow comprises one or more of integrating business rules, integrating clinical trials processes' connectivity, assuring proper sequencing of critical path elements, assuring proper change management, assuring proper logistics, and collecting the information in accordance with the approved study protocol;* (see at least Thangaraj page 19 line 27 – 32; page 15 line 12 - 18 and page 20 line 25 - 31);

- *assuring data integrity of the clinical information comprises one or more of validating that the information is accurate, determining that the information is relevant to the study being conducted, assuring that the information is in a standardized coding system, assuring that the information is normalized, verifying that the information is complete, assuring that the information is uncorrupted, and assuring that the information is unaltered;* (see at least Thangaraj page 3 line 5 – 18 and page 11 line 15 - 19);
- *the assuring the security of the clinical information comprises preventing access to the information by unauthorized non-stakeholders;* (see at least Thangaraj page 3 line 5 - 8);
- *the assuring the privacy of the clinical information comprises preventing access to the information by unauthorized stakeholders;* (see at least Thangaraj page 3 line 5 - 8).

CLAIM 38

Thangaraj as shown discloses a clinical trial management system with the following limitations:

- *providing a first report of treatment allocation for all enrolled subjects;* (see at least Thangaraj page 25 line 5 - 15);
- *providing a second report on all used and unused investigational products;* (see at least Thangaraj page 25 line 5 - 15);
- *locking a clinical trial database after completion of all case report forms;* (see at least Thangaraj page 23 line 28 - 34);
- *performing a final analysis on the locked clinical trial database;* (see at least Thangaraj page 25 line 5 - 15);

- *notifying at least one stakeholder of completion of the clinical trial;* (see at least Thangaraj page 23 line 28 - 34);
- *drafting a final clinical study report;* (see at least Thangaraj page 11 line 15 – 19; page 11 line 26 – 33 and page 12 line 24 - 34)

CLAIM 39

Thangaraj as shown discloses a clinical trial management system with the following limitations:

- *creating a digital dashboard for a stakeholder;* (see at least Thangaraj page 17 line 9 - 12);
- *displaying a category of information common to all stakeholders on the digital dashboard; and displaying a category of information specific to the stakeholder on the digital dashboard;* (see at least Thangaraj page 13 line 14 - 33).

CLAIMS 40 - 47

Thangaraj as shown discloses the limitations shown above relative to Claim 39. Thangaraj also discloses the following limitations:

- *the stakeholder comprises one of sponsor, regulator, investigator, site, patient, and monitor;* (see at least Thangaraj page 3 line 10 – 17 and page 9 line 32 to page 10 line 7);
- *the category of information common to all stakeholders comprises one or more of an email application, links to Web sites, references to trial information, announcements, and alerts;* (see at least Thangaraj page 22 line 18 – 32);
- *the category of information specific to a sponsor stakeholder comprises one or more of study documents, site performance, action items, financial metrics, good will metrics,*

safety records, and sponsor performance metrics; (see at least Thangaraj page 12 line 24 – 34 and page 13 line 14 – 33);

- *the category of information specific to a regulator stakeholder comprises one or more of study documents, site performance, action items, and site adverse events;* (see at least Thangaraj page 12 line 24 – 34 and page 13 line 14 – 33);
- *the category of information specific to an investigator stakeholder comprises one or more of monitoring schedule, action items, monthly and daily schedule, site performance metrics, queries, milestones, and site adverse events;* (see at least Thangaraj page 12 line 24 – 34 and page 13 line 14 – 33);
- *the category of information specific to a site stakeholder comprises one or more of monitoring schedule, action items, site statistics, site performance metrics, waiting response, safety training, pending investigational new drug reports, special handling information, efficacy summary, and safety summary;* (see at least Thangaraj page 12 line 24 – 34 and page 13 line 14 – 33);
- *the category of information specific to a patient stakeholder comprises one or more of investigator profile, information about the study disease, patient record, reminders, instructions, and study documents;* (see at least Thangaraj page 12 line 24 – 34 and page 13 line 14 – 33);
- *the category of information specific to a monitor stakeholder comprises one or more of multi-site monitoring, milestones, adverse events, action items, queries, and multi-site*

performance metrics; (see at least Thangaraj page 12 line 24 – 34 and page 13 line 14 – 33).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thangaraj et al. (WO 01/093160 A1) and in further view of Buonocore et al. (US PGPUB 2004/0010418 A1).

Thangaraj as shown discloses the limitations shown above relative to Claim 11. Thangaraj does not specifically disclose the following limitations, however, Buonocore does:

- *the trial conduct application further comprises an encounter scheduler and tracker component, wherein the encounter scheduler and tracker component integrates the scheduling of clinical trial-related visits with routine physician office visits and captures physician-patient encounter data from each clinical trial-related visit;* (see at least Buonocore paragraph 0009, 0028, 0029 and 0031).

Buonocore discloses clinical trial management system which includes patient scheduling capability. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the clinical trial management system of Thangaraj so as to have included patient scheduling capability, in accordance with the teaching of Buonocore, in order to increase the efficacy of a clinical trial, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

18. Claims 24 – 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buonocore et al. (US PGPUB 2004/0010418 A1).

CLAIM 24

Buonocore as shown discloses a clinical trial management system with the following limitations:

- *designing a schedule of subject visits based on a clinical trial protocol;* (see at least Buonocore paragraph 0009);
- *enrolling a subject based on inclusion and exclusion criteria of the clinical trial protocol;* (see at least Buonocore paragraph 0028);

- *scheduling subsequent visits for the subject;* (see at least Buonocore paragraph 0029 and 0031);
- *providing alerts that the enrolled subject should be sent reminders in advance of subsequent visits of the subject;* (see at least Buonocore paragraph 0017);
- *generating a checklist upon a visit by the subject;* (see at least Buonocore paragraph 0040);
- *documenting the checklist of items completed and not completed after the visit by the subject;* (see at least Buonocore paragraph 0040 and 0045).

Buonocore does not specifically disclose the following limitations:

- a *checklist*;
- *documenting the checklist of items completed and not completed*;
- *documenting cancelled and missed visits by the subject;*
- *dropping the subject if a number of visits cancelled and missed exceeds a threshold;*
- *notifying the subject when the number of visits cancelled and missed exceeds the threshold; and*
- *documenting the dropping of the subject when the number of visits cancelled and missed exceeds the threshold.*

However, the system of Buonocore does disclose

- a request for response from the clinical trial participant
- that the system tracks requests not completed and

- tracks missed events related to the clinical trial and notifies the investigator for the purpose of retaining or correcting the deviation by a clinical trial participant.

Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to include these features because doing so could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIMS 25, 26 and 29

Buonocore as shown discloses the limitations above as they relate to Claim 24. Buonocore also discloses the following limitations:

- *the subsequent visits comprise one or more of an office visit, laboratory tests, x-ray tests, procedures, and preparation for procedures;* (see at least Buonocore paragraph 0030 and 0031);
- *the checklist comprises one or more of prompting a principal investigator review and signature, generating patient instructions, generating a coordinator checklist, checking laboratory results, checking pathology results, checking microbiology results, and checking study reports;* (see at least Buonocore paragraph 0011 and 0031);
- *checking a designed schedule of subject visits for consistency with a clinical trial protocol and rules of informed consent;* (see at least Buonocore paragraph 0009);
- *collecting subject information in a manner compliant with industry regulations and standards;* (see at least Buonocore paragraph 0028);
- *checking the collected' subject information against inclusion and exclusion criteria of business logic rules;* (see at least Buonocore paragraph 0026);

- *changing subject information coding to indicate enrolled and non-enrolled subjects;* (see at least Buonocore paragraph 0029);
- *checking lead time of a scheduled visit against all other scheduled visits for conflicts;* (see at least Buonocore paragraph 0029);
- *assuring that reminder calls are made and documented;* (see at least Buonocore paragraph 0029);
- *generating subject instructions at time of scheduling a subject visit;* (see at least Buonocore paragraph 0029);
- *alerting at least one stakeholder if a scheduled visit is missed or cancelled;* (see at least Buonocore paragraph 0029).

Buonocore does not specifically disclose the following limitations:

- *generating a checklist automatically at beginning of the subject visit; notifying at least one stakeholder at the beginning of the subject visit; alerting at least one stakeholder before a scheduled subject visit;*
- *generating a checklist to track proper compliance with follow-up procedures;*
- *alerting at least one stakeholder if the subject is dropped for exceeding a threshold of missed and cancelled visits.*
- *assuring that due diligence is shown and documented in regard to cancelled and missed visits by subjects;*
- *assuring that proper methods are used to drop a subject from the clinical trial; assuring the proper notice is given to a dropped subject;*

- *assuring the subject information of a dropped subject is properly identified in the system.*

However, the system of Buonocore does disclose

- a request for response from the clinical trial participant
- that the system tracks requests not completed and
- tracks missed events related to the clinical trial and notifies the investigator for the purpose of retaining or correcting the deviation by a clinical trial participant.

Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to include these features because doing so could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

CLAIMS 27 and 28

Buonocore as shown discloses the limitations above as they relate to Claim 24. Buonocore does not specifically disclose the following limitations:

- *the threshold of visits cancelled and missed comprises three visits;*
- *the notifying the subject comprises sending a certified letter to the subject.*

However, Examiner takes **Official Notice** that it is old and well known in the art to drop a participant after missing a certain threshold of visits and to notify them of that action. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify Buonocore with the **Official Notice** taken so that participant who fail to comply with the trial protocol be dropped after missing a threshold of visits and be notified of that action in order to

increase the efficacy of a clinical trial, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

19. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buonocore et al. (US PGPUB 2004/0010418 A1) and in further view of Thangaraj et al. (WO 01/093160 A1).

CLAIM 31

Buonocore as shown discloses the limitations shown above relative to Claim 30. Buonocore does not specifically disclose the following limitations, however, Thangaraj does:

- *the stakeholder comprises one of sponsor, regulator, investigator, site, patient, and monitor;* (see at least Thangaraj page 3 line 5 – 8 and page 9 line 32 to page 10 line 7).

Thangaraj discloses clinical trial management system which includes a stakeholder definition. Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the clinical trial management system of Buonocore so as to have included a stakeholder definition, in accordance with the teaching of Thangaraj, in order to clarify the roles of clinical trial stakeholders, since so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **John A. Pauls** whose telephone number is **571-270-5557.** The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JERRY O'CONNOR** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

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/JOHN A. PAULS/
Examiner, Art Unit 3686
Date: 21 April, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
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